JUDGE HELLERSTEIN

12 CIV 2238

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES DISTRICT COUNCIL 37 HEALTH & SECURITY PLAN and SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated,

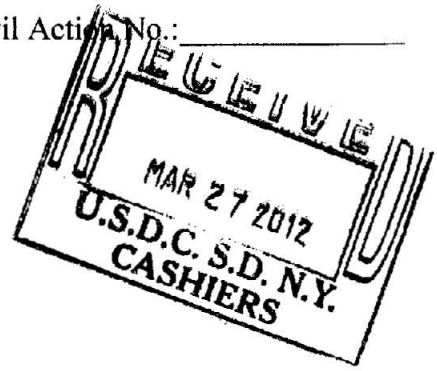
Plaintiffs,

v.

BRISTOL-MYERS SQUIBB CO. and OTSUKA AMERICA PHARMACEUTICAL, INC.,

Defendants.

Civil Action No.: _____



CLASS ACTION COMPLAINT
AND JURY DEMAND

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I. INTRODUCTION

1. Plaintiffs American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan and Sergeants Benevolent Association Health and Welfare Fund bring this proposed class action against defendants Bristol-Myers Squibb Co. and Otsuka America Pharmaceutical, Inc. for their unlawful prescription co-pay subsidy program. Defendants have paid, and continue to pay, undisclosed kickbacks to privately-insured individuals so that those health plan members will choose defendants' branded drug, Abilify, instead of less-expensive therapeutic alternatives. Defendants knowingly caused health benefit providers to pay for more prescriptions of this drug than they otherwise would have, and caused falsely-inflated drug reimbursement rates to be reported to, and imposed on, the members' health benefit providers for these subsidized prescriptions.

2. Cost-sharing provisions in prescription drug benefit plans unite the financial interests of the health insurer with the interests of its beneficiaries. Requiring health plan members to pay a small portion of the high cost of a branded prescription drug — either a co-pay or co-insurance — provides a reasonable, personal incentive for privately-insured individuals to choose less-costly, usually generic, medications, and drives down the cost of the much larger residual portion paid by the health benefit providers.

3. In response to cost-sharing provisions, defendants began subsidizing members' co-payments for their key brand name prescription drug. These subsidies are designed to undermine cost-sharing arrangements. By eliminating or reducing member co-pays for branded drugs, plan members have no incentive to use less-expensive generic drugs, and health benefit providers end up paying for more costly branded drugs. A recent study estimated that these kickbacks will increase health benefit providers' prescription drug costs by *$32 billion* over the next ten years.

4. Each co-pay subsidy program is one size fits all, involving a formulaic, rote discount that applies regardless of the details of the patient's cost-sharing arrangements. Presenting a co-pay subsidy card to a pharmacist triggers a secondary form of insurance — provided by the manufacturer — that functionally reduces the price of the drug without disclosing that price reduction to the insurer. Each and every subsidy is calculated and processed electronically; the health benefit plans receive electronic records falsely indicating that the members paid their personal cost-share obligations, yet the manufacturer's digital paper trail discloses the truth — that the copayments were subsidized by the manufacturer.

5. DC 37, Sergeants, and the proposed class allege two bases for defendants' liability. First, federal racketeering law prohibits this form of insurance fraud. Effectuated by each of the defendant brand name drug companies through agreements with servicing companies, the routine waiver of co-payments means that the true costs for reimbursement of the routinely subsidized drug are less than represented by the drug manufacturer and pharmacy, and thus the amount of reimbursement imposed on the health benefit plan is inflated. The brand name defendants commit this fraud through their service provider and the fraud is accomplished through the use of United States mail and wires. This suit seeks damages under 18 U.S.C. §1964(c) for violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1962 (c) and (d).

6. Second, federal antitrust law prohibits this form of commercial bribery. Under Section 2(c) of the Robinson-Patman Act, a seller cannot lawfully pay undisclosed kickbacks to someone who makes a decision to purchase a product that is paid for by another. 15 U.S.C. § 13(c). Defendants subsidize members' co-pays to induce them to purchase defendants' branded drug instead of less-expensive therapeutic alternatives; health benefit providers then pay for the

much more expensive branded drug. Consumers who use defendants' co-pay savings cards or coupons are not told that their insurers are paying much more for defendants' brand-name drug.

7. This suit seeks damages under Section 4 of the Clayton Act (15 U.S.C. § 15) for overpayments caused by defendants' undisclosed kickbacks.

II. PARTIES

8. Plaintiff American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan ("AFSCME DC 37" or "DC 37") is based in New York and administers a variety of self-insured supplemental health and welfare benefits to its more than 125,000 members, which include current and retired employees of the City of New York and their dependents. DC 37's offerings include a prescription drug benefit. At all relevant times, DC 37's prescription drug benefit plan has contained cost-sharing provisions for plan members, provisions intended to place a personal financial obligation on the plan members through a tiered co-payment that places branded drugs in a less preferred position than other commonly-prescribed therapeutic or AB-rated generic alternatives. During the course of defendants' subsidy scheme, DC 37 paid for the much more expensive brand name drug in circumstances where its members' cost-sharing obligations were not paid by them personally but were subsidized by defendants. As a result of defendants' illegal subsidies, DC 37 purchased more of defendants' expensive brand name drug than it otherwise would have. DC 37 was injured as a result of defendants' unlawful conduct.

9. Plaintiff Sergeants Benevolent Association Health and Welfare Fund ("Sergeants") is an employee welfare benefit plan located in the State of New York. Sergeants is a not-for-profit benefit fund that provides comprehensive health care benefits to approximately 12,000 active and retired New York City Police Department sergeants and their dependents. At all relevant times, Sergeants' prescription drug benefit plan has contained cost-sharing provisions

for plan members, provisions intended to place a personal financial obligation on the plan members through a tiered co-payment that places branded drugs in a less preferred position than other commonly-prescribed therapeutic or AB-rated generic alternatives. During the course of defendants' subsidy scheme, Sergeants paid for the much more expensive brand name drug in circumstances where its members' cost-sharing obligations were not paid by them personally but were subsidized by defendants. As a result of defendants' illegal subsidies, Sergeants purchased more of defendants' expensive brand name drug than it otherwise would have. Sergeants was injured as a result of defendants' unlawful conduct.

10. Defendant Bristol-Myers Squibb Co. ("BMS") is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 345 Park Avenue, New York, New York. BMS jointly markets the branded drug Abilify with defendant Otsuka. From in or around 2010 through the present, BMS and Otsuka subsidized plan member co-pays in order to increase the number of Abilify prescriptions purchased by health benefit providers.

11. Defendant Otsuka America Pharmaceutical, Inc. ("Otsuka") is the holding company for the U.S. operations of Japan's Otsuka Pharmaceutical Co., Ltd. Otsuka is a corporation organized and existing under the laws of the State of Delaware with headquarters at 2440 Research Boulevard, Rockville, Maryland. Otsuka jointly markets the branded drug Abilify with defendant BMS. From in or around 2010 through the present, BMS and Otsuka subsidized plan member co-pays in order to increase the number of Abilify prescriptions purchased by health benefit providers.

12. McKesson Corporation, with headquarters at One Post Street in San Francisco, California, administers the co-pay subsidy program for Abilify (marketed jointly by BMS and Otsuka). McKesson's co-pay program, called LoyaltyScript, "serve[s] more than 17,000 patients

every day" and has "saved patients more than $335 million in out-of-pocket prescription costs." According to McKesson, the LoyaltyScript program allows manufacturers to "[i]ncrease market share through co-pay discounts that capture new customers" and "[g]ain valuable insight into program utilization to maximize [their] marketing ROI." McKesson is *not* named as a defendant in this action but is an unnamed co-conspirator.

III. STANDING

13. Plaintiffs DC 37 and Sergeants have standing to bring this lawsuit for three independent reasons.

14. First, during the relevant time periods, DC 37 and Sergeants paid for prescriptions of Abilify where the defendants' co-pay subsidy was not reflected in the overall reimbursement amount charged by the pharmacy and paid by DC 37 and Sergeants.

15. Second, during the relevant time periods, DC 37 and Sergeants paid for prescriptions of Abilify where the member's co-pay was subsidized by defendants.

16. Third, during the relevant time periods, DC 37 and Sergeants, paid for prescriptions that, but for defendants' co-pay subsidies, would have otherwise been written for and filled with less expensive medications.

IV. JURISDICTION AND VENUE

17. This action arises under section 4 of the federal RICO statute (18 U.S.C. § 1964) and under section 2(c) of the Robinson Patman Act (15 U.S.C. § 13), a 1936 amendment to the Clayton Act (15 U.S.C. §§ 12-27); the Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 18 U.S.C. § 1964 (RICO), and 15 U.S.C. § 15(a) (Robinson-Patman).

18. The activities of the defendants were within the flow of, were intended to, and did have a substantial effect on interstate commerce of the United States. Venue, therefore, lies within this District under 28 U.S.C. § 1391.

19. Venue is also proper under the special venue provisions of the federal racketeering and antitrust laws, 18 U.S.C. § 1965 and 15 U.S.C. § 22, as defendant BMS is headquartered in this District and defendants BMS and Otsuka transact business within this District.

V. FACTS

A. Branded drug manufacturers have attacked the private prescription drug co-pay system.

20. Branded drug manufacturers have attacked the private prescription drug co-pay system by subsidizing plan members' co-pays in order to undermine cost-sharing arrangements between health benefit providers and those they insure. These co-pay subsidy programs reduce or eliminate individuals' co-pays regardless of their financial need.[1] Whether characterized as coupons, rebates, subsidies, or kickbacks, these payments to plan members interfere with health plans' cost-sharing provisions and intentionally influence prescription drug choices. The programs are designed, quite specifically, to reduce or eliminate privately-insured individuals' personal payment obligations so that they choose the brand name drugs and their health benefit providers foot the bill.

21. Although co-pay subsidy programs vary as to the drugs covered and the specific amount of the subsidy or rebate, all programs work the same way. Individuals enroll in drug-specific programs online.[2] Individuals provide basic information (name, address, and whether they have private health insurance coverage) and the drug company mails them a wallet-size card that includes instructions to pharmacists regarding how to process covered prescriptions. Some drug companies allow individuals to immediately print cards using their home computers.

[1] Co-pay subsidy programs are, by definition, primarily or exclusively for privately-insured individuals.

[2] In the infancy of these programs, drug companies gave co-pay subsidy cards to doctors and pharmacists, who in turn gave the cards to patients. Some cards are still distributed this way but most are available online.

22. Members then present their card at the pharmacy with a prescription, and the pharmacist processes the prescription according to the instructions on the card. The pharmacist enters information into a computerized data management system in order to submit a claim, first keying in the patient's health insurance information in the primary insurance field. Insurance information regarding the transaction for that particular individual and his/her insurer is transmitted back to the pharmacist from the insurance company or its pharmacy benefit manager ("PBM"), including information about the member's co-pay or co-insurance obligation. The pharmacist then enters information from the co-pay card system into the secondary insurer field. Information regarding the extent of the co-pay subsidy or rebate is similarly computed, but only after the patient's primary insurance is processed (and billed).

23. The pharmacist and PBM use the reimbursement benchmark, which the brand name drug company provides to the reporting agency, to calculate the usual charge (*i.e.*, unreduced by the amount of the subsidy) to the health benefit insurer for the procurement of that prescription drug. The pharmacist and PBM do so without advising the insurer that, at the same time, the plan member's personal cost share obligation is being picked up by the drug's manufacturer. As a result, the private health benefit provider pays for the medication at its usual (but in fact now inflated) cost, and it does so without being told that the usual cost-share obligation has not been paid by the enrollee, but rather by the brand manufacturer.

24. In effect, defendants bribe plan members to choose their branded drug over less-expensive therapeutic alternatives in order to get the health benefit plan to pay for the bulk of the cost of their more expensive branded drug. From the member's perspective, the branded drug and therapeutic alternatives cost close to, if not exactly, the same amount. But the price of the

health benefit plan's share of the therapeutic alternative with the lower co-pay and the branded drug with the higher co-pay may differ by a factor of ten.

> **An Example:** A brand drug company offers a co-pay card giving privately-insured individuals the opportunity to save up to $25 off their cost share for each prescription filled for a particular, and expensive, medication for chronic illness. The plan member brings the co-pay card to his pharmacy and provides his insurance card and co-pay card to the pharmacist. The pharmacist processes information from the insurance card and transmits it to the PBM. The PBM recognizes the drug as a TIER 3 brand drug for the plan member and relays a $70 obligation to the insurer and a $30 co-pay obligation to the plan member.
>
> In a separate transaction, the pharmacist processes information from the co-pay savings card or coupon. The co-pay card program administrator recognizes the $30 co-pay and covers $25 thereof, leaving $5 for the plan member to pay out-of-pocket (while the pharmacy charges the remaining $25 to the manufacturer through the co-pay card program administrator). The insurer is required to pay for the branded drug as if it were priced at $100, even though the usual cost for these subsidized transactions is $75, and even though there are equally appropriate, less expensive medications available at prices around 1/3 the cost of the branded drug.

25. By their terms, defendants' co-pay subsidy program (i) applies to individuals who are privately insured under a prescription drug plan that requires personal cost sharing by the member for retail prescription drugs such as the one covered by the co-pay subsidy program, (ii) undermine the contractual insurance arrangement between the insurer and the insurer's member by reducing or eliminating the personal cost-share feature of the insurance contract, (iii) causes the health benefit provider to pay for more units of the expensive co-pay subsidy drug than it would have if the defendants had not interfered with the parties' performance of the contract, and (iv) increase the overall burden on the plan for providing benefits to its members.

26. Co-pay subsidy programs are also effectively a form of secondary insurance, whereby defendants agree to cover a portion of the privately-insured individual's prescription drug expenses. Prescription drug benefit plans, along with the formularies under which they operate, set forth appropriate balances in coverage terms, means of access, payment obligations

and cost-sharing provisions for medications. Prescription drug insurance contracts — whether they are wholly private plans or plans that are privately-administered but publicly subsidized (such as Medicare Part D plans or managed Medicaid drug plans) — are governed by myriad federal and state laws and regulations which ensure that the plans properly balance the availability of prescription drugs and sensible financial terms. Defendants' co-pay subsidies, function as unregulated secondary health insurance that, after payment by the primary insurer, swoop in to relieve the plan member of specifically-designed *personal* financial obligations. By doing so, defendants' co-pay subsidies fundamentally change the nature of the regulated relationship between health insurers and members. Although defendants' co-pay subsidies function as a form of secondary insurance, defendants do not comply with the myriad laws governing the provision of health insurance.

B. Cost sharing is critical to the effective functioning of health care in the United States.

27. In most economic systems, the person who *selects* the product or service is also the person who *pays* for the product or service. Health care is a big, notable exception. Typically, a physician or other health care provider (in consultation with the patient) *chooses* the medication or medical procedure, the patient *receives* the care or consumes the medication, and a public or private health benefit provider *pays* for the services and medication. The payer is separated from those who make the purchasing decision. Without cost-sharing provisions — such as percentage co-insurance or graduated co-pays — those choosing the prescription drugs (the patients in consultation with their physicians) have little or no incentive to choose less costly drugs.

28. Public and private health insurance relies on cost sharing to re-align the interests of patients, health care providers, and health benefit providers. Although cost-sharing techniques

vary by type and amount, they all have the singular purpose of imposing a personal financial obligation on the covered individual in order to encourage price sensitivity and achieve the range of acceptable balance between coverage and cost. Insured individuals often face point-of-service charges for medical services and prescription drugs. These include deductibles (amounts that must be paid before some or all services are covered), co-payments (fixed dollar amounts), and/or co-insurance (a percentage of the charge for services). Health benefit providers impose on different degrees of cost sharing for different services: annual deductibles for medical services, a separate deductible for prescription drugs, hospital and outpatient co-insurance, co-pays for physician office visits, and/or out-of-pocket maximum amounts.

29. Cost sharing is therefore fundamental to almost all medical spending in the United States. Whether it be for hospital, physician, dental, or other health care provider services, for employer-sponsored or individual plans, for medical procedures, or for prescription drugs, numerous forms of cost sharing are imposed as a critical component of public and private health plans in order to carefully incentivize cost-conscious use of medical services and products while at the same time affording appropriate access to medical care.

C. The routine waiver of cost-sharing obligations, including co-payments and co-insurance, for medical services and products is unlawful.

30. Recognizing the ubiquity and necessity of cost sharing, federal and state statutes declare the practice of routinely waiving co-payment obligations for medical services and products to be unlawful.

31. First, routinely waiving co-pays constitutes financial inducements that are deemed illegal kickbacks. The waiver is in effect a form of payment that induces the use of medical services or products offered by the party that routinely waives co-pays. The routine waiver of

co-pays amounts to health care fraud and is criminal.[3] In the public arena, physicians, hospitals, and medical products providers who receive payment through Medicare or Medicaid programs and routinely waive co-payments or deductibles may be held in violation of federal and state anti-kickback statutes. The federal anti-kickback statute prohibits the payment of remuneration (any kickback, bribe or rebate) when it is knowingly paid to induce business that will be paid for by a federal health care program.[4] And the routine waiver of co-payments in the Medicare and Medicaid areas forms the basis for a violation of the False Claims Act and the Civil Monetary Penalties Law.[5]

32. Second, the routine waiver of co-payments constitutes a form of insurance fraud.[6] When cost sharing is routinely waived, the true acquisition cost for the medical service or product is not the stated or reported price being charged to health benefit providers, but rather the price *after deduction for the routinely waived co-payments*. The unlawfulness of this form of insurance fraud is well-known to physicians of any stripe, hospitals, and other health care providers. Physicians and other providers have been criminally prosecuted for routinely waiving co-payments yet still charging the insurer the inflated, pre-waiver price. The American Medical Association has long issued the following warning: "physicians should be aware that forgiveness

[3] 18 U.S.C. § 1347: Health care fraud ("Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. . . . [A] person need not have actual knowledge of this section or specific intent to commit a violation of this section."); 18 USCS § 1349: Attempt and conspiracy ("Any person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense . . . .").

[4] 42 U.S.C. § 1320a-7b(b).

[5] *See* 42 U.S.C. § 1320a-7a; 31 U.S.C. § 3729.

[6] *See, e.g., Kennedy v. Connecticut Gen. Life Ins. Co.*, 924 F.2d 698, 699 (7th Cir. Ill. 1991) (appellant was required to collect co-payments from the insured patients if he wished to receive payment under an insurance plan that required co-payments: "Providers of medical care may seek to increase their business by promising to waive . . . co-payments. Patients prefer the lower outlays, but waivers annul the benefits of the co-payment system"); *id.* at 702 ("[a]llowing the provider to 'pay' the co-payment to himself is just another way to describe waiver of co-payments").

or waiver of copayments may violate the policies of some insurers, both public and private . . . . Routine forgiveness or waiver of copayments may constitute fraud under state and federal law."[7]

33. Third, the defendants' co-pay subsidy program would violate federal and state anti-kickback statutes. The federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)(2)) provides:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly … to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

34. The Massachusetts False Health Care Claims Act (MASS. GEN. LAWS ch. 175H § 3) similarly provides:

> [A]ny person who offers or pays any remuneration, including any bribe or rebate, directly or indirectly . . . to induce any person to purchase . . . any good, facility, service, or item for which payment is or may be made in whole or in part by a health care insurer, shall be punished by a fine of not more than ten thousand dollars, or by imprisonment in a jail or house of correction for not more than two and one-half years or in the state prison for not more than five years, or by both such fine and imprisonment, and may be held liable in a civil action.

35. Defendants knowingly offer and pay remuneration in the form of co-pay subsidies to patients in order to induce them to purchase defendants' brand name drug. The federal government has acknowledged that co-pay subsidy programs may well violate the federal antikickback statute.[8]

36. Defendants know that subsidizing a co-payment for a drug paid for by the Federal government or a Massachusetts resident would violate the statutes. Although defendants'

[7] American Medical Association Opinion 6.12, issued June 1993, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion612.page.

[8] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70624 (Nov. 22, 2005) ("[W]e conclude that pharmaceutical manufacturer PAPs [Patient Assistance Programs] that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute.").

program purports to exclude Medicaid and Medicare recipients and Massachusetts residents in the fine print, on information and belief, the program has been, and is being, used by persons who participate in those federal and state programs. For example, many individuals are enrolled in and receive prescription drugs under Medicare Part D; but because Medicare Part D benefits are sponsored by private health benefit providers, individuals enrolling in defendants' program may report themselves as privately insured, *not* as Medicare patients. Similarly, many Medicaid patients receive their care through managed Medicaid programs run by private health insurers, not state agencies; again, when enrolling in defendants' co-pay subsidy program, these individuals may report themselves as privately insured simply by clicking the appropriate "no" buttons on defendants' websites.

37. If Medicare's ban on co-pay coupons were not enforced, costs to the Part D program would increase by $18 billion over the period from 2012 to 2021.

38. Massachusetts is the only state that statutorily bans co-pay coupons for private payers. Were it to repeal that law, a recent study suggests that prescription drug costs for employers and other plan sponsors in Massachusetts would increase by $750 million by 2021. Many states that do not explicitly prohibit these programs will see similar — or even larger — increases. For example, Illinois plans are expected to spend nearly $1.4 billion extra on prescription drug costs as a result of co-pay coupons or programs during that time; Florida, New York, California and Texas will spend an extra $2 billion each in the next decade as a result of the same programs.[9]

[9] Visante, "How Copay Coupons Could Raise Prescription Drug Costs By $32 Billion Over the Next Decade", Nov. 2011, *available at* http://www.pcmanet.org/images/stories/uploads/2011/Nov2011/visante%20copay%20coupon%20study.pdf ("Visante Study"), at 13-15.

D. Health benefit providers use cost sharing to cope with ever-increasing prescription drug costs.

39. Cost sharing has particular importance in the coverage for prescription drug benefits. In 2000, prescription drug spending in the U.S. exceeded $142 billion. By 2009, spending ballooned to more than $300 billion. This increase in drug spending is in large part due to high and rising prices for the most well-known and most often used brand name drugs. In recent years, the price of the most widely used brand name drugs increased annually at approximately 6% to 9% — two or three times the general rate of inflation. The drug at issue here has seen significant price increases in recent years.

1. Public and private health benefit providers use tiered cost sharing to reduce spending on prescription drugs.

40. For both public and private health benefit providers, prescription drug cost sharing is widely and effectively used, and has been for many years.

41. In the public realm, beneficiaries under Medicaid have, for years, been required to pay a portion of the cost of their medications, despite the fact that Medicaid eligibility is limited to low income and disabled individuals. Similarly, even beneficiaries under Medicare Part B — generally the elderly receiving critical physician or in-home services — have been required to share the costs of their medications. And, more recently, beneficiaries under Medicare Part D are required to make co-payment or co-insurance payments under terms specified by Medicare Part D plan sponsors.

42. Most health insurance in the United States is provided by private health benefit providers. In the private realm, cost sharing for prescription drugs is similarly widespread. Under private health insurance plans, individuals and employers pay premiums to health benefit providers and, in turn, the health benefit providers agree to pay all or a portion of the cost of

needed medical services and products.[10] Well over 95% of covered employees in employer-sponsored private health benefit plans have prescription drug benefits. More often than not, the form of cost sharing is a co-payment rather than co-insurance, although co-insurance has steadily increased over time.

43. Drug benefit cost-sharing provisions have evolved over the decades, with the key innovation being the differentiation of co-payments among differing drugs. When drug insurance was first introduced, the plan members typically paid the same co-insurance (or co-pay) rate for any drug. Over time, that changed, and the price now depends on the "tier" in which the drug is placed. The early tiered plans typically had only two tiers, but most plans now have three or more tiers. In recent years, an increasing number of plans have created a fourth tier of drug cost sharing, which may be used for lifestyle drugs or expensive biologics:

> **Generic drugs:** A drug product that is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.
>
> **Preferred drugs:** Drugs included on a formulary or preferred drug list; for example, a brand name drug without a generic substitute.
>
> **Non-preferred drugs:** Drugs not included on a formulary or preferred drug list; for example, a brand name drug with a generic substitute.
>
> **Fourth-tier drugs:** New types of cost-sharing arrangements that typically build additional layers of higher co-payments or co-insurance for specifically identified types of drugs, such as lifestyle drugs or biologics.
>
> **Brand name drugs:** Generally, a drug product that is covered by a patent and is thus manufactured and sold exclusively by one firm. Cross-licensing occasionally occurs, which allows an additional firm to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name or trademark remains with the original manufacturer's product.

[10] In the United States, most private health insurance is paid at least in part by employers, although it is also common for employees to contribute to the cost of their premiums. Truly individual health insurance policies may also be purchased.

44. The number of plans requiring some form of cost sharing that differentiates between forms of drugs has steadily increased, but has plateaued in recent years. Almost 90% of privately-insured individuals have some formula for tiered cost sharing; over 75% are enrolled in plans with three, four, or more tiers of cost sharing for prescription drugs.

45. A drug's tier placement largely depends on its cost: Tier 1 drugs are less expensive, usually generic, drugs. More expensive, usually brand name, drugs are placed on higher tiers. Health benefit providers encourage members to choose Tier 1 drugs by imposing a lesser co-pay than that imposed for Tier 2 drugs. Tiered co-payments and co-insurance (which is a percentage of the overall cost of the drug at retail) thereby provide reasonable personal financial incentives to individuals to use equally effective, but less costly, medications. If a drug is placed on Tier 1, the member pays the pharmacy a relatively small co-payment. If the drug is placed on Tier 2, then the co-payment or coinsurance obligation increases. The difference in the co-payment/coinsurance between Tier 2 and Tier 1 incentivizes the plan member to choose the less costly medication. If a drug is a Tier 3 drug, a therapeutic alternative or generic equivalent will invariably exist for the medication in Tier 2 and/or Tier 1.

46. Another major, long term trend has been the increasing *amount* of the co-payment or co-insurance required. Over the last decade, average retail co-payment levels increased by about 62%. Average co-payments for Tier 2 drugs increased by about 127%. Average co-payments for Tier 3 drugs increased the most, from about $17.53 in 1998 to about $42.95 in 2009, an increase of about 149%. As expected, the 2009 average retail co-payment for Tier 4 drugs is even greater, at $62.11.

47. Widespread use of cost sharing for prescription drugs, the increasing trend of multi-tier cost sharing and the increasing amounts for co-payments and co-insurance are, of

course, no accident. Although other forms of prescription drug cost reductions may have more dramatic results — including the market entry of AB-rated generic equivalents — cost sharing has defined, measurable results. Cost sharing provides personal financial incentives to plan members to select the most cost-appropriate medications; these incentives work.

48. Patients — and to a lesser extent, their doctors — are sensitive to differences in co-payment requirements, particularly for maintenance drugs that they anticipate taking for long or indefinite periods of time. According to a 2007 literature review published in the Journal of the American Medical Association, *every 10% increase in cost sharing (through co-payments or co-insurance) reduces drug spending by 2 - 6%*. And drug companies are well aware that plan members consider co-pay differences when choosing prescription drugs: "[t]he patient, I will tell you, is economically very, very sensitive to co-pays, and a $5, $10, $20, $25 co-pay matters," says Abbott Laboratories Chief Executive Miles White.[11]

2. Branded drugs are expensive; differentiated cost sharing for branded and generic drugs help health benefit providers and health plan members curtail prescription drug spending.

49. Generic drugs thus play a critical role in health benefit providers' attempts to curb ever-escalating prescription drug costs. Generic drugs are almost always significantly less expensive than their branded counterparts. On average, generic prescriptions cost payers $16, preferred brand prescriptions cost $118, and non-preferred brands cost $124. Tiered cost-sharing provisions thus incentivize generics by imposing a lower co-pay or co-insurance for generics than for brands.

50. AB-rated generics are, by definition, substitutable for their branded equivalents. All fifty states have laws that permit pharmacies to substitute AB-rated generics for their branded

[11] Event Brief of Q2 2009 Abbott Earnings Conference Call – Final, FD (Fair Disclosure) Wire (July 15, 2009).

counterparts when an AB-rated equivalent is available. Health benefit providers create strong incentives for plan members to demand generic drugs by imposing different co-pays for branded and generic drugs. Consequently, more than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. 2010 IMS industry data — the industry's gold standard — reflects that, on average, AB-rated generics capture 80% of the brand's sales within the first six months.

51. In addition to AB-rated generics, a brand name drug may also have generic therapeutic alternatives. Therapeutic alternatives are *not* bioequivalent to their brand-name counterparts, but are alternative medicines that treat the same medical condition in a similar way. As an example, Pfizer's blockbuster drug Lipitor belongs to a therapeutic class of drugs called "statins" used to treat high cholesterol. But because statins work in similar ways, a patient and/or physician may determine that another statin, such as generic simvastatin, lovastatin, and pravastatin, is a sensible cost-effective alternatives — particularly since (without a co-pay subsidy) the cost to the patient by reason of the tiered co-payment system would be much higher for Lipitor than for a generic statin.

E. Co-pay subsidies work: health plan members fill prescriptions for branded drugs instead of generics and health benefit providers pay much higher prices for these subsidized prescriptions.

52. These kickbacks work. According to a 2011 study undertaken for the Pharmaceutical Care Management Association and based on evidence from drug coupon administrators, "25% of [co-pay] coupon use results in a couponed drug being used instead of a preferred brand or generic that might have been used in the absence of the coupon."[12] More than 100 million prescriptions were associated with co-pay coupons in 2010, accounting for 11% of

[12] Visante Study at 11.

brand prescriptions.[13] These numbers will grow exponentially: at current trends, the number of prescriptions associated with co-pay subsidy programs will increase by 15% per year, reaching 500 million prescriptions and approximately 50% of non-specialty brand prescriptions by 2021.[14] All told, employers and other plan sponsors will likely spend an extra $32 billion on prescription drugs as a result of these co-pay subsidy programs over the next decade.[15]

53. It is estimated that pharmaceutical companies spend $4 billion on co-pay cards and coupons annually.[16] Drug manufacturer Amgen has stated publicly that spending on its co-pay subsidy programs amounts to about *1% of its total product sales*; in the first quarter of 2010, Amgen spent $35 million on co-pay subsidy programs. This amount is likely to increase as more co-pay programs are created and more plan members take advantage of existing programs.

54. Brand-name pharmaceutical manufacturers know that these co-pay subsidy programs work: these programs are now a regular part of life cycle planning for branded drugs, typically launching two to three years before AB-rated generic equivalents of the brand name drug are expected to enter the market. The manufacturer tries to maximize the number of prescriptions written by physicians, filled by members, and paid for by both members and health benefit providers before pharmacies begin automatically substituting the AB-rated generic equivalents for the brand name drug.

55. Health benefit providers have seen significant increases in the number of prescriptions filled for brand name drugs that have co-pay subsidy programs. Recently, co-pay

[13] *Id.* at 12.

[14] *Id.*

[15] *Id.* at 3, 13-15.

[16] http://blogs.forbes.com/matthewherper/2011/03/16/how-bargain-lipitor-could-raise-health-costs/ (citing Mason Tenaglia, managing director of the Amundsen Group, a consulting firm that has studied the cards). *See also* Visante study at 6.

subsidy administrators have anecdotally reported that their unnamed clients, manufacturers of branded drugs, earn between a 4:1 and 6:1 return on their investments in these programs.

56. The attack on prescription drug co-payment system is open and notorious. Large branded drug companies reflexively subsidize co-payments for many brand name drugs simply because they are nearing patent expiry. Co-payment subsidy administration has become a cottage industry. Program administrators boast about the effective and efficient methods by which they have wiped out the personal financial incentives of plan enrollees to select, in consultation with their physicians, less costly medications.

57. Drug companies, including defendants, not only determine the price at which wholesalers or large retailers will purchase prescription drugs from them, but also control the reimbursement benchmark used to determine the amount to be paid for the drugs by public and private health benefit providers. Either by directly determining the so-called average wholesale price (or "AWP") or by determining a related price benchmark known as the wholesale acquisition price (or "WAC") that reporting agencies use to mathematically determine the AWP, branded drug manufacturers cause to be published the widely-used and nearly ubiquitous benchmark prices for payments and reimbursements that health benefit providers make to pharmacies for branded, retail-channel drug products.

58. Branded drug manufacturers, including defendants, know that the reported benchmark that they control is required to be a reasonably fair estimation of the actual price for the ingredient cost of the drug to the retailer. When a prescription for a privately-insured individual is filled at the retail level (*i.e.*, a pharmacy), the pharmacy charges the member's plan for the ingredient cost of the drug plus a dispensing fee. The amount to be charged for the ingredient cost is based on a percentage discount from the benchmark (*e.g.*, AWP minus 14% for

all branded drugs). Thus, the stated benchmark represents the price that all participants — the health benefit provider, its pharmacy benefit manager, the pharmacy and the manufacturer — understand is a reasonable estimate of the actual cost to the pharmacy on which the payer's reimbursement to the pharmacy is based. Of course, if a cost-sharing provision exists for the member's prescription drug plan, then the cost share (*e.g.*, co-payment or co-insurance) is deducted from the amount owed by the plan to the pharmacy and is imposed on the member as a payment to the pharmacy. However, for subsidized co-pays, the true benchmark is less, resulting in an inflated payment by the health insurers.

59. Routinized co-pay subsidy programs constitute commercial bribery because the programs pay undisclosed kickbacks to plan enrollees to select expensive medications that are paid for by prescription drug benefit providers.

60. Routinized co-pay subsidy programs constitute insurance fraud because routine waiver of co-payments reduces true acquisition costs, yet drug manufacturers withhold co-payment information, do not decrease the applicable reimbursement benchmark for the drugs, and cause inflated payments to be imposed upon private prescription drug benefit providers.

F. Defendants BMS and Otsuka subsidized health plan members' co-pays for Abilify.

61. Defendants designed and implemented the program described below (referred to as the "co-pay subsidy program"), relating to the brand name drug Abilify (the "co-pay subsidy drug").

62. Defendants' co-pay subsidy program described below alters the carefully calibrated co-payment system negotiated by health benefit providers and their members. It is intended to steer unsuspecting members toward the more expensive brand name drug when less expensive therapeutic alternatives are available in generic form, with generic price tags.

1. BMS and Otsuka's faced substitution competition from less expensive therapeutic alternatives after the launch of Abilify.

63. On November 15, 2002, the FDA approved Abilify (aripiprazole) to treat schizophrenia. By 2005, sales of Abilify had topped $1 billion. In 2010, Abilify was the sixth highest selling drug in the United States, with sales of over $3.5 billion. In mid-2010, however, BMS noticed that Abilify was experiencing an increased level of abandonment at the pharmacy level. Patients would take their prescriptions to the pharmacy and then decide not to fill them.[17] For patients with new prescriptions for Abilify, the abandonment rate was as high as 22-23%. BMS assured its investors: "Obviously, we have stepped in as quickly as we can to assist patient [sic] from a co-pay perspective to drive that forward." It is easy to see why patients might have suffered from sticker shock. In 2009, the average monthly cost of Abilify was $589.[18]

64. Less expensive therapeutic alternatives to Abilify include risperidone (Risperdal) and olanzapine (Zyprexa).

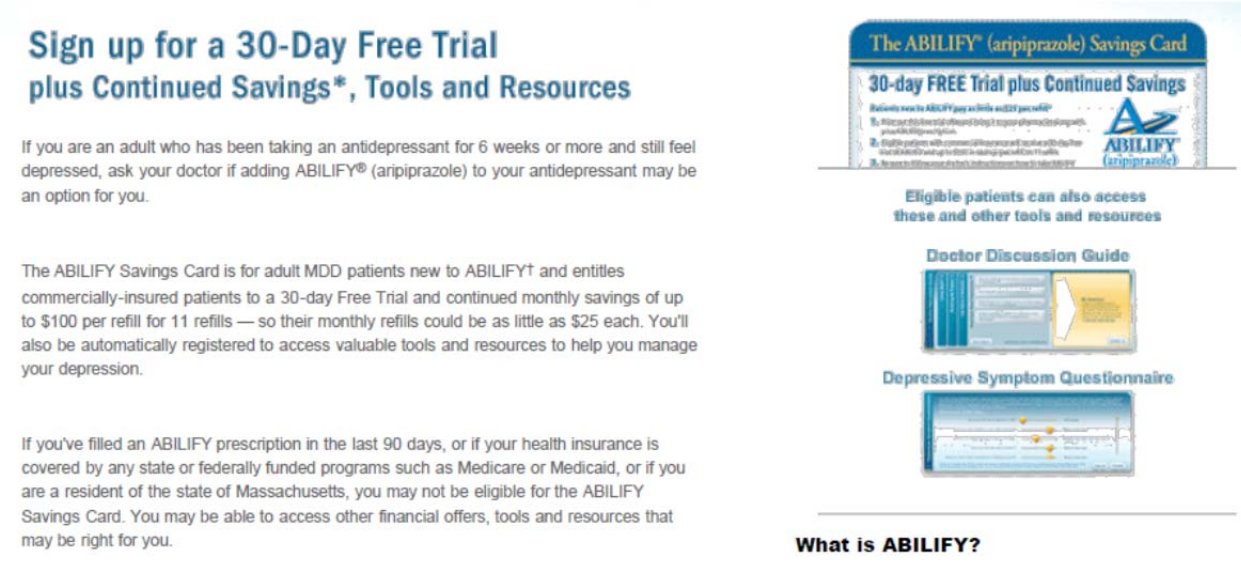
2. In the wake of substitution competition from less expensive alternatives, BMS and Otsuka created the Abilify Savings Card co-pay subsidy program.

65. To combat the competition it was facing from generic alternatives, in or around 2010, BMS and Otsuka created the Abilify Savings Card:[19]

[17] Q3 2010 Bristol-Myers Squibb Earnings Conference Call - Final FD (Fair Disclosure) Wire (Oct. 26, 2010).

[18] Consumers Union, Treating schizophrenia and Bipolar disorder: The Antipsychotics, Comparing Effectiveness, Safety, and Price (June 1993), two-page summary of full report, both *available at* http://www.consumerreports.org/health/best-buy-drugs/antipsychotics.htm.

[19] https://www.abilify.com/depression/tools/sign-up.aspx (Dec. 7, 2011).



Sign up for a 30-Day Free Trial
plus Continued Savings*, Tools and Resources

If you are an adult who has been taking an antidepressant for 6 weeks or more and still feel depressed, ask your doctor if adding ABILIFY® (aripiprazole) to your antidepressant may be an option for you.

The ABILIFY Savings Card is for adult MDD patients new to ABILIFY† and entitles commercially-insured patients to a 30-day Free Trial and continued monthly savings of up to $100 per refill for 11 refills — so their monthly refills could be as little as $25 each. You'll also be automatically registered to access valuable tools and resources to help you manage your depression.

If you've filled an ABILIFY prescription in the last 90 days, or if your health insurance is covered by any state or federally funded programs such as Medicare or Medicaid, or if you are a resident of the state of Massachusetts, you may not be eligible for the ABILIFY Savings Card. You may be able to access other financial offers, tools and resources that may be right for you.

66. As the patient website (until very recently) explained, the card "entitle[d] commercially-insured patients to a 30-day Free Trial and continued monthly savings of up to $100 per refill for 11 refills - so their monthly refills could be as little as $25 each." Patients were only eligible for these savings if they had not filled more than one prescription for Abilify in the last ninety days.

67. In or around December 2011, BMS and Otsuka extended their offer to $100 off per refill for *seventeen* refills. Patients are not eligible, however, if they have filled more than one prescription for Abilify within the last *sixty* days.

68. The Abilify Savings Card program is not a need-based program. It is open to all patients with commercial prescription insurance coverage for Abilify. A patient can sign up by answering a few short questions and providing his or her date of birth, name, address and e-mail address on BMS's website: https://www.abilify.com/depression/tools/sign-up.aspx.

69. The Abilify Savings Card is advertised directly to individuals on national television. For example, in commercials for Abilify that aired on CBS on August 29, 2011 and

October 24, 2011, patients were directed to "learn more about the free trial offer at www.ABILIFYoffer.com."

3. BMS and Otsuka's Abilify Savings Card program specifically provides that it does not apply to Medicare or Medicaid patients or residents of Massachusetts.

70. The website for the Abilify Savings Card states that, if "your health insurance is covered by any state or federally funded programs such as Medicare or Medicaid, or if you are a resident of the state of Massachusetts, you may not be eligible for the ABILIFY Savings Card." To enroll in the program, patients must check a box stating that they have "[c]ommercial prescription insurance through an employer-sponsored or similar private health plan." The website and the fine print on the card also state that "[t]o be eligible for this Free Trial Offer with Continued Savings, patients must have commercial prescription insurance, and not have prescriptions paid by any state or federally funded programs such as Medicare, Medicaid, Medigap, VA, DOD, or Tricare," and that the card is "not valid where prohibited by law, taxed, or restricted."

4. The Abilify Savings Card functions as an unlawful form of secondary health insurance.

71. The fine print on the back of the Abilify Savings Card states that it "is not an insurance card," but the front of the card specifically instructs pharmacists on how to process the card as "secondary coverage":

> For the Pharmacist . . . If primary coverage exists, input card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response.

72. Despite BMS and Otsuka's fine print disclaimer, the card clearly functions as a form of secondary insurance coverage.

G. Defendants hired McKesson to run their co-pay subsidy program.

73. Defendants depend on cooperation from both pharmacies and its program administrator to conduct the co-pay subsidy program. Defendants compensate both pharmacies and its co-pay benefit administrator for their efforts. Defendants and its co-conspirator administrator process co-pay subsidy claims through a "shadow claims system" that hides the subsidies from health benefit providers.

74. For prescription drugs, plan members present their co-pay cards or coupons along with their health insurance cards (which include the prescription drug plan) at the pharmacy. An individual's primary insurance is processed first, establishing the individual's co-pay or co-insurance amount[20] and the price of the drug that will be billed to the health benefit provider.

75. The pharmacist then processes the co-pay card or coupon associated with the co-pay subsidy program. The pharmacist enters into the pharmacy computers information on the co-pay card as though it were a form of secondary insurance. The pharmacist notes the amount of the co-pay that will be subsidized by the defendant and conveys that information to a co-pay card program administrator who reimburses the pharmacy on the defendant's behalf.[21] The plan member pays out-of-pocket the difference between his or her co-payment (or co-insurance) and the amount subsidized by the defendant. The pharmacist then charges the health benefit provider the full amount of the health benefit provider's usual payment for the branded drug in question, *i.e.*, the health benefit provider pays an amount for the co-pay subsidy drug's purchase as if the plan's member had made full personal payment of his/her cost-sharing obligation.

[20] For plan members with a co-insurance responsibility, pharmacists determine the dollar amount to be paid by the member. Sometimes, this amount is referred to, inaccurately, as a "co-pay."

[21] The administrator pays pharmacies for all co-pay subsidies on the manufacturer's behalf every fourteen to twenty-eight days. The manufacturer repays the administrator on a similar schedule.

76. During a transaction *without* the use of the unlawful co-pay subsidy, the pharmacy reports data to the health benefit provider (or its PBM) that enables the provider to know the claim, drug dispensed, amount paid by the plan, amount of co-payment/co-insurance paid, and other data. In a transaction *with* the use of the subsidy, *the information transmitted to the health benefit provider does not include any disclosure that a subsidy was paid*; the plan member's cost-sharing obligation is simply reported to the benefit provider as having been paid.

77. As F. Everett Neville, chief trade relations officer at Express Scripts, one of the country's largest PBMs, told the New York Times in January 2011: "[t]he payer doesn't know, and the P.B.M. doesn't know . . . We have no ability to stop it and no ability to prohibit it."

78. Defendants hired McKesson (the "administrator") to administer the Abilify co-pay subsidy program. McKesson is *not* named as a defendant in this action but is an unnamed co-conspirator for purposes of RICO and antitrust violations.

79. McKesson's co-pay subsidy administration program, called LoyaltyScript, "serve[s] more than 17,000 patients every day" and has "saved patients more than $335 million in out-of-pocket prescription costs."[22] According to McKesson, the LoyaltyScript program allows manufacturers to "[i]ncrease market share through co-pay discounts that capture new customers" and "[g]ain valuable insight into program utilization to maximize your marketing ROI."[23]

80. McKesson holds a patent, applied for on March 31, 2006, for a means of processing co-pay subsidies at the point of sale — that is, when the patient brings his prescription to the pharmacy.[24] McKesson's patent contemplates electronically receiving claims

[22] http://sites.mckesson.com/mprs/solutions/loyaltyscript_difference.shtml.

[23] http://sites.mckesson.com/mprs/solutions/loyaltyscript_benefits.shtml

[24] U.S. Patent No. 7,957,983 (issued June 7, 2011).

from pharmacies that are separate and distinct from claims that are submitted to members' health benefit plans:

> What is claimed is: 1. An apparatus comprising: one or more processors configured to receive *an electronic claim transaction* submission at an administrator in response to a purchase transaction of a client at a point of sale of a healthcare provider, *a primary payer separate and distinct from the administrator* also receiving the electronic claim transaction submission from the healthcare provider to initiate adjudication of a primary claim for *an offset of at least a portion of a cost associated with the purchase transaction*, wherein the one or more processors are configured *to adjudicate*, in response to receiving the electronic claim transaction submission and *separate and distinct from the primary claim, one or more services of a program of an administrator to which the client is enrolled*, the purchase transaction being applicable to the program, the one or more services including one or more marketing services or interventions, wherein the one or more processors are also configured to trigger provision of the one or more services to the client in response to adjudication of the one or more services.[25]

81. McKesson's patent asserts that the pharmaceutical industry had not previously identified a method of providing cost-saving benefits in light of the variability of co-pays:

> [previously,] monetary incentives for prescription fulfillment have been limited to a uniform value for a particular product offer. *For insured patients, pharmaceutical marketers have sought the ability to vary the incentives based upon the individual patient's co-pay amount*, which can vary considerably across prescription benefit plans based upon individual patient coverage, cost sharing tiers, drug formulary design, and plan exclusions. To date, *no solutions have been identified to address this variability in patient cost-share* amounts on a patient-specific basis in real time using the mail-in rebate, debit card or credit card mechanisms.[26]

82. The patent goes on to say that McKesson's invention solved the industry's "problem" of not being able to undermine health benefit provider's cost-sharing provisions:

[25] *Id.* at Claim 1 (emphasis added).

[26] *Id.* at Background of the Invention (emphasis added).

> [T]he [monetary] secondary benefit may offset at least a portion of the out-of-pocket expense for a purchase transaction applicable to the respective program. …[T]he secondary benefit may be provided in real time at the point of sale … by linking secondary benefit with the dispensing and purchase of a medication. The secondary benefit may also be tied to a patient's actual primary benefit, such as by determining the secondary benefit as a percentage of a primary benefit (further offsetting the cost associated with a purchase transaction).[27]

83. McKesson's patent notes that "the adjudications *may* occur sequentially, such that adjudication at the primary payer occurs prior to adjudication at the administrator,"[28] implying that the adjudications *could instead* take place simultaneously or in the opposite order. Yet Figure 4 (reproduced below) shows two separate feedback loops, one in which the "healthcare provider" (*i.e.* the pharmacy) submits the "primary claim adjudication" to the "primary payer" (*i.e.* bills the health benefit plan) and a second in which the "healthcare provider" separately submits a "service request" to the co-pay subsidy administrator. The co-pay subsidy administrator then provides "Backstage Support Services:" confirming that the patient is enrolled in the program, paying the "secondary benefit" (the co-pay subsidy) to the pharmacy, and submitting information about the patient's prescription to the "sponsor" (the drug manufacturer):

[27] *Id.* at Summary of the Invention.

[28] *Id.* at Secondary Benefits Provided by Administrator (emphasis added).

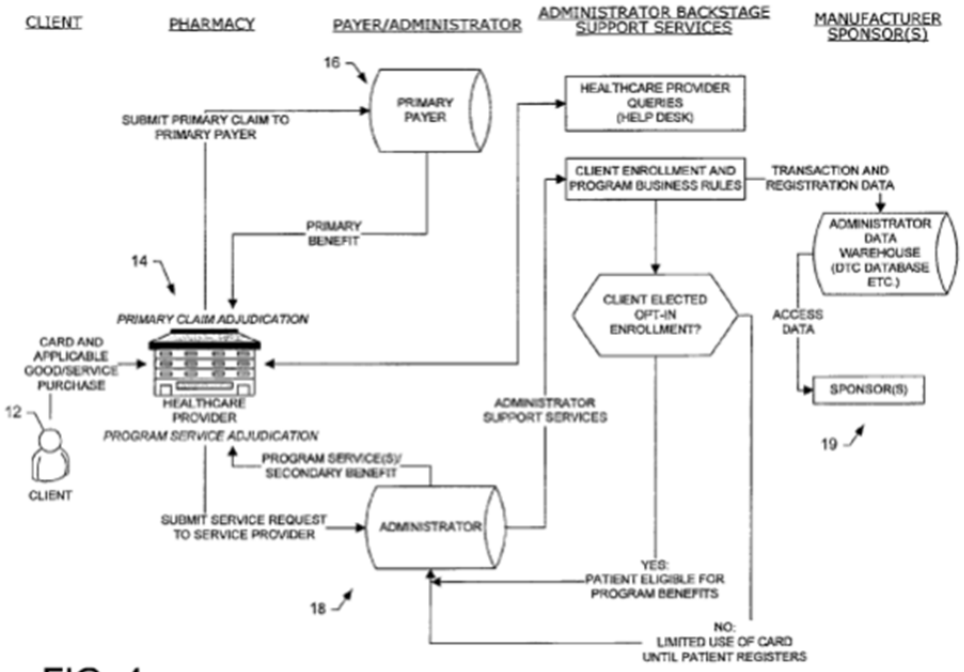


FIG. 4.

H. Health benefit providers do not know, and cannot know, when defendants subsidize their members' co-pays.

84. Health benefit providers are generally aware that drug companies offer co-pay subsidy programs. But health benefit providers do not know, and cannot know, which of the prescriptions that they have paid for have been subsidized. Pharmacists process subsidies as instructed by the defendants and its co-conspirator administrator, and they do not tell health benefit providers or PBMs when a prescription has been subsidized. Defendants, however, possess detailed records of each and every subsidized prescription. The extent of the injury to DC 37, Sergeants, and the class can easily be determined through discovery of defendants' co-pay subsidy program records.

I. Defendants' co-pay subsidy program intentionally interferes with the relationship between health benefit providers and their members.

85. By providing undisclosed kickbacks to reduce or eliminate the cost-sharing mechanism in thousands of health insurance contracts for widely used maintenance prescription

drugs, defendants unfairly undermine health benefit providers' best attempts to control prescription drug costs. Pharmacy and Thereapeutics ("P&T") committees arrive at formulary placement decisions after considerable decision-making, in an effort to address overall prescription drug costs as a burden on the delivery of quality health care. Even small co-pay subsidies meddle with the cost share balance so carefully struck by P&T committees in formulary tier structures and cost containment provisions in prescription drug benefit plans. Defendants offer such sweeping bribes that they often effectively reduce the co-pay for their branded drug to *less* than the average co-pay for therapeutic or AB-rated generic alternatives, thereby completely neutralizing health benefit providers' contractual agreed tiered formulary structure.

86. Defendants intend to interfere with health plans' cost-sharing provisions. For example, McKesson's patent (discussed above) specifically contemplates a co-pay subsidy program that absorbs the entire amount of the patient's cost-share obligation:

> "[A] program could be designed to capture the patient's cost share requirement for a drug as determined by the patient's prescription drug coverage and subsequently provide the patient an additional discount on the final prescription cost. . . . Although fixed discounts may be offered, such as a flat $5.00 discount, other techniques may be used, such as variable discounts which reduce all patient cost share amounts, regardless of individual drug benefit coverage, to a fixed dollar amount."[29]

87. The co-pay subsidy kickbacks also force other potential short or long-term changes in available prescription drug coverage. Without a means of enabling cost *sharing* (and make no mistake about it, defendants' co-pay subsidy program prevents plans and their members from agreeing to effective sharing programs), plans are left to consider wholesale cost *shifting*, under which the benefit provider pays *none* of the cost of a branded drug, and the member pays

[29] *Id.* at Detailed Description of the Invention.

all of the cost, when alternatives to a branded drug exist. At base, defendants have unfairly, deceptively and improperly interfere with health insurance providers' ability to effectively contract for appropriate cost-sharing provisions in insurance contracts.

88. Finally, as described above and despite defendants' fine-print disclaimers to the contrary, the co-pay subsidy kickbacks are an unlawful form of secondary health insurance.

J. Defendants' co-pay subsidy program involves misrepresentations sent via mail and the wires.

1. Defendants could not run their program without using the mail and wires.

89. Defendants make individuals aware of their co-pay subsidy program through the mail and wires. Defendants advertise their co-pay subsidy program on the Internet, splashing links across websites devoted to their brand name drug. Defendants advertise their program in magazines and on network television.

90. The Abilify Savings Card is advertised directly to individuals on national television. For example, in commercials for Abilify that aired on CBS on August 29, 2011 and October 24, 2011, patients were directed to "learn more about the free trial offer at www.ABILIFYoffer.com."

91. Defendants have individuals sign up for their program via the wires. Most patients sign up to participate in the program online, filling out information that is transmitted to the defendants via the Internet.

92. Defendants send the physical co-pay cards to individuals, doctors, and pharmacies via the mail.

93. McKesson's patent for methods of administrating these co-pay subsidy programs expressly contemplates pharmacies, co-pay subsidy program administrators, and manufacturers of sponsored drugs communicating through "one or more data networks, such as a local area

network (LAN), a metropolitan area network (MAN) and/or a wide area network (WAN) (e.g. Internet) and . . . one or more voice networks, such as a public-switched telephone network (PSTN)."

94. The co-pay subsidy enterprises do, in fact, use the mail and wires to implement this program. Defendants and their co-conspirator administrator use the wires to have the pharmacy contact the administrator about the number of subsidized prescriptions filled and the amount subsidized for each prescription, and the administrator in turn contacts the manufacturer and communicates the subsidy information to the manufacturer.

95. Defendants also use the mail and wires to send money to the administrator, and the administrator sends money to the pharmacies to effectuate reconciliation and reimburse the pharmacy for recognizing the co-pay subsidies.

96. These communications between pharmacies, the administrator, and defendants occur tens of thousands of times per year. Defendants and their co-conspirator administrator possess information about the specific dates of transactions, information which defendants have withheld from health benefit plans.

2. Defendants convey two distinct misrepresentations via the mail and wires.

97. Defendants and their co-conspirator administrator make misrepresentations via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when, as instructed by the defendants, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies. These transactions necessarily involve the use of the wires.

98. Defendants make additional misrepresentations via the mail and wires when defendants report benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

VI. CLASS ALLEGATIONS

99. Plaintiffs bring this action pursuant to Federal Rule of Civil Procedure 23, on behalf of themselves and a national class defined as:

> All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of a co-pay subsidy drug prescribed to natural persons covered by such contract, policy, or plan, and who paid for at least one prescription for Abilify that was subsidized by defendants' co-pay subsidy program.

100. The class period runs from when defendants started offering the Abilify co-pay subsidy program until defendants stop offering the program. The precise class period will be identified through discovery.

101. Excluded from the class are (i) defendants, defendants' legal representatives, officers, directors, assignees, predecessors, and successors, (ii) federal and state governmental entities administering prescription drug programs under Medicare, Medicaid, and or other federally or state-sponsored programs, and (iii) counsel for plaintiffs and the class's self-funded health benefit plans (if any).

102. All class members have suffered, and will continue to suffer, harm and damages as a result of defendants' unlawful and wrongful conduct.

103. Defendants' co-pay subsidies are specifically targeted to undermine the cost-share provisions in those contracts.

104. Class members can be precisely determined from defendants' records, the records of the administrator of defendants' co-pay subsidy program, and pharmacy records. Members of the class themselves are unable to identify the subsidized prescriptions. However, defendants possess information about the subsidized prescriptions, including the name and specific identifying information about each participating member and the pharmacy where the

prescription was filled. The pharmacy has a record of both the amount of subsidy and the individual's health plan. The administrator also has this information, as well as the accumulated results of the programs through all pharmacies. No uninjured parties will be included within the class because each member can be determined with specificity, based on actual transactional data.

105. The fact of injury or damages to each class member can also be reasonably estimated from existing data. Aggregate damages to the class as a whole can reasonably be estimated from existing data, and commonly-used mechanisms by which to allocate that award among class members exist.

106. The class consists of thousands of private health benefit providers. These providers are geographically dispersed throughout the United States. The disposition of all claims in a single action will substantially benefit all parties and the Court.

107. Plaintiffs DC 37 and Sergeants are the proposed class representatives.

108. The claims of DC 37 and Sergeants are typical of the claims of the class. Both DC 37 and Sergeants purchased drugs on behalf of its members whose cost-share obligations were subsidized by defendants. DC 37 and Sergeants, like all class members, paid for too many co-pay subsidy drug prescriptions as a result of defendants' subsidies. DC 37 and Sergeants will fairly and adequately protect the interests of the class. DC 37 and Sergeants have retained counsel with substantial experience prosecuting nationwide third party payor class actions. DC 37, Sergeants, and their counsel are committed to vigorously prosecuting this action on behalf of the class and have the financial resources necessary to do so.

109. The factual and legal issues regarding defendants' alleged misconduct are common to all class members and represent a common thread of misconduct resulting in injury to DC 37, Sergeants, and the class. Common questions of law and fact include:

a. Whether defendants engaged in a course of conduct that improperly increased plaintiffs' and other class members' drug costs;

b. Whether defendants engaged in a kickback scheme to increase plaintiffs' and other class members' drug costs;

c. Whether defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud plaintiffs and other members of the class;

d. Whether defendants formed an enterprise for the purpose of effectuating its fraudulent scheme;

e. Whether defendants used the U.S. mails and interstate wire facilities and commerce to carry out this fraudulent scheme;

f. Whether defendants engaged in conduct that violated the federal racketeering laws as alleged herein;

g. Whether defendants engaged in conduct that violated federal antitrust laws as alleged herein;

h. Whether plaintiffs and the other members of the class were injured by the conduct of defendants and, if so, the appropriate class-wide measure of damages; and

i. Whether plaintiffs and the other members of the class are entitled to injunctive relief.

110. Prosecution of separate actions by individual class members would create the risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for defendants.

111. Defendants have acted on grounds generally applicable to all class members in that defendants' anticompetitive and fraudulent actions uniformly impacted all class members. Accordingly, injunctive relief is necessary to protect all class members from further injury.

112. Plaintiffs know of no difficulty that would prevent this case from being maintained as a class action. A class action is the superior method for fairly and efficiently adjudicating this controversy. The cost of litigating a single action would prevent most class members from bringing suit individually. Class action treatment will, among other things, allow a large number of similarly situated entities to prosecute their common claims in a single forum, thus avoiding the unnecessary duplication of resources that numerous individual actions would require. Moreover, class action treatment allows injured payors, including smaller plans with limited means, to seek redress on claims that might be impracticable to pursue individually. Thus, absent a class action, there would be no remedy at law for thousands of injured entities. And absent a class action, there would be no mechanism for imposing uniform equitable injunctive relief to the class as a whole.

VIII. CAUSES OF ACTION

COUNT ONE
SUBSTANTIVE RICO VIOLATION
(18 U.S.C. § 1962(c))

113. This Count alleges substantive violations of RICO (as provided in 18 U.S.C. § 1962(c)), relating to the co-pay subsidy program described above, and is asserted against defendants on behalf of plaintiffs and the class.

114. COUNT ONE is asserted against defendants BMS and Otsuka for the Abilify co-pay subsidy program. The Abilify co-pay subsidy enterprise is an association-in-fact comprised of defendants BMS and Otsuka and unnamed co-conspirator McKesson.

115. This enterprise is referred to as the "co-pay subsidy enterprise." The drug Abilify is referred to as the "subsidized drug." McKesson is referred to as the "administrator."

116. Plaintiffs, members of the class, defendants, and the unnamed co-conspirator are all "persons" as defined by 18 U.S.C. § 1961(3).

A. Defendants and their co-conspirator administrator formed association-in-fact RICO enterprise.

117. For purposes of this claim, the RICO co-pay subsidy enterprise alleged herein is an associations-in-fact within the meaning of 18 U.S.C. § 1961(4). Defendants and their co-conspirator administrator, including their directors, employees and agents formed association-in-fact enterprise. This co-pay subsidy enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purpose of maximizing sales of subsidized drugs by unlawfully interfering with cost-sharing provisions.

118. Within the co-pay subsidy enterprise there are contractual relationships, financial ties, and continuing coordination activities between defendants and their co-conspirator administrator.

119. On information or belief, members of each co-pay subsidy enterprise have communicated repeatedly over the course of several years to carry out their common purposes, and have entered into, monitored, and enforced contractual and/or agency arrangements regarding payment and the delivery of services. Defendants hired the administrator to carry out the program.

B. The co-pay subsidy enterprise engaged in and affected interstate commerce.

120. The co-pay subsidy enterprise engaged in and affected interstate commerce because it involved thousands of transactions at hundreds of pharmacies all over the country and is attendant to defendants' marketing, distribution, and sale of the subsidized drug across state boundaries and throughout the United States.

121. During the class period, the illegal conduct and wrongful practices carried out by members of each co-pay subsidy enterprise (including defendants and the administrator) were effectuated by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products, and funds through the U.S. mails and interstate wire facilities. In particular, the administrator transmitted pharmacy data to defendants, and defendants transmitted funds to the administrator, who transmitted funds to the pharmacies.

C. Defendant associated with its co-pay subsidy enterprise.

122. The nature of the co-pay subsidy scheme required defendant to form and participate in an enterprise. Defendants hired their co-conspirator administrator and monitored and enforced this contractual arrangement regarding payment and the delivery of services. Each

of these actions was necessary to, or helpful in, each co-pay subsidy enterprise's ability to carry out its goal of interfering with plaintiffs' and class members' cost-sharing provisions and causing plaintiffs and class members to be charged an inflated reimbursement rate for subsidized prescriptions.

D. The co-pay subsidy enterprise engaged in a pattern of racketeering activity.

123. Defendants conducted and participated in the affairs of the co-pay subsidy enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341 (mail fraud) and 18 U.S.C. § 1343 (wire fraud).

1. The co-pay subsidy enterprise engaged in scheme to defraud.

124. The co-pay subsidy enterprise engaged in an intentional scheme to defraud plaintiffs and the class by interfering with their cost-sharing provisions, causing them to pay for prescriptions of the subsidized drug that they would not otherwise have paid for, and causing them to pay an inflated rate for each subsidized prescription. These transactions necessarily involve the use of the wires.

125. The co-pay subsidy enterprise engaged in an intentional scheme to defraud plaintiffs and the class by causing misrepresentations to be made via the wires at the time of the point of sale transaction — that is, when the member presents the co-pay card at the pharmacy — when, as instructed by the defendants, the pharmacist electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies (as instructed by defendants). These transactions necessarily involve the use of the wires.

126. The co-pay subsidy enterprise engaged in an intentional scheme to defraud plaintiffs and the class by reporting benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays. These transactions necessarily involve the use of the mail and wires.

127. Defendants knew that entities like plaintiffs and members of the class have cost-sharing programs to reduce the use of brand drugs by their plan members. The purpose and intent of defendants' co-pay subsidy scheme was to overcome such restrictions on brand drug purchases and to cause plaintiffs and the class to pay for more for the subsidized drug at artificially inflated prices.

2. The co-pay subsidy enterprise used interstate communications systems to carry out this scheme.

128. The nature of this scheme necessarily required members of the co-pay subsidy enterprise to communicate directly and frequently by the U.S. mails and interstate wire facilities.

129. Many of the precise dates of the co-pay subsidy enterprises' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to defendants' records. An essential part of the successful operation of the co-pay subsidy enterprise was defendants' ability to conceal the use of subsidies from DC 37, Sergeants, and the class at the point of sale.

130. During the class period, defendants exerted control over the co-pay subsidy enterprise, and in violation of § 1962(c) of RICO, they conducted and participated in the conduct of the affairs of the co-pay subsidy enterprise, directly or indirectly, in the following ways:

i. Defendants conceived of and implemented the unlawful co-pay subsidy program;

ii. Defendants directly controlled the creation and distribution of marketing, sales, and other materials used to inform patients and physicians about the unlawful co-pay subsidy program;

iii. Defendants set the terms of the program, including eligibility criteria, amount of subsidy, and number of subsidies;

iv. Defendants caused the administrators to administer the program without informing health benefit plans about the subsidies; and

v. Defendants instructed and caused pharmacies to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions by instructing the pharmacy to process the co-pay card as though it were a form of secondary insurance.

131. Defendants' pattern of racketeering likely involved tens of thousands of separate instances of use of the U.S. mails or interstate wire facilities to carry out the unlawful co-pay subsidies. Each of these fraudulent mailings and interstate wire transmissions and/or each transaction to charge health benefit plans an inflated reimbursement rate for subsidized prescriptions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). These violations constitute a "pattern" of racketeering activity within the meaning of 18 U.S.C. § 1961(5) in which defendants intended to defraud plaintiffs and members of the class.

E. The unlawful activity proximately injured plaintiffs and the class.

132. Defendants' participation in the affairs of the co-pay subsidy enterprise, through a pattern of racketeering activity, have directly and proximately caused DC 37, Sergeants, and members of the class to be injured in their business or property. Plaintiffs, members of the class, and others reasonably relied upon a belief that their members were paying their share of prescription drug costs (as determined by the cost-sharing provisions of their particular health plans) and that pharmacies were reporting and charging a reimbursement rate that accurately reflected the price defendants actually charged for the subsidized drugs.

133. Defendants profited directly from the co-pay subsidy scheme in the form of increased sales of the subsidized drug that plaintiffs and the class would not otherwise have purchased but for defendants' interference with their cost-sharing programs. As a direct and

proximate result of defendants' overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(c), plaintiffs and the class have been and are continuing to be injured in their business or property.

134. Plaintiffs and members of the class were injured in their property by reason of these violations in that plaintiffs and members of the class have paid for an increased number of prescriptions for the subsidized drug as a result of the co-pay subsidy enterprises' substantive RICO violations. By reason of the unlawful acts engaged in by each co-pay subsidy enterprise, plaintiffs and the class have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendants' racketeering activity.

135. Under § 1964(c) of RICO, defendants are liable to DC 37, Sergeants, and members of the class for three times the damages sustained, plus the cost of bringing suit and reasonable attorneys' fees.

COUNT TWO
CONSPIRACY TO VIOLATE RICO
(18 U.S.C. § 1962(d))

136. This Count alleges conspiracies to violate RICO (as provided in 18 U.S.C. § 1962(d)), relating to the co-pay subsidy program described above, and is asserted against defendants on behalf of DC 37, Sergeants, and the class.

137. COUNT TWO is asserted against defendants BMS and Otsuka for the Abilify co-pay subsidy program. The Abilify co-pay subsidy enterprise is an association-in-fact comprised of defendants BMS and Otsuka and unnamed co-conspirator McKesson.

138. This enterprise is referred to as the "co-pay subsidy enterprise." The drug Abilify is referred to as the "subsidized drug." McKesson is referred to as the "administrator."

139. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." Defendants have violated Section 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of their ongoing conspiracies was to conduct or participate in, directly or indirectly, the conduct of the affairs of the co-pay subsidy enterprise through a pattern of racketeering activity.

140. Defendants adopted the goal of furthering or facilitating the criminal endeavor of the co-pay subsidy enterprise minimally by agreeing to facilitate some of the acts leading to the substantive offenses and by, as described above, directly engaging in numerous overt and predicate fraudulent racketeering acts in furtherance of each conspiracy, as described above.

141. Defendants not only agreed to the objectives of the 18 U.S.C. § 1962(d) violations of RICO by conspiring to violate 18 U.S.C. § 1962(c), but were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

142. By hiring an administrator to carry out the co-pay subsidy scheme, defendants minimally engaged in overt acts in furtherance of the scheme as well as actual predicate violations of mail or wire fraud. As a direct and proximate result of defendants' overt acts and/or predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), plaintiffs and members of the class have been and are continuing to be injured in their business or property.

143. Plaintiffs and members of the class were injured in their property by reason of these violations in that plaintiffs and members of the class have paid for an increased number of prescriptions for the subsidized drug as a result of the co-pay enterprises' conspiracy to violate 18 U.S.C. § 1962(c).

144. By reason of the unlawful acts engaged in by the co-pay subsidy enterprise, plaintiffs and the class have suffered ascertainable loss and damages. These injuries were directly and proximately caused by defendants' racketeering activity.

145. By virtue of these violations of 18 U.S.C. § 1962(d), defendants are liable to DC 37, Sergeants, and the class for three times the damages sustained, plus the cost of this suit and reasonable attorneys' fees.

COUNT THREE
COMMERCIAL BRIBERY IN VIOLATION OF ROBINSON-PATMAN ACT
(15 U.S.C. § 13 (c))

146. This Count alleges commercial bribery in violation of the Robinson-Patman Act (as provided in 15 U.S.C. § 13 (c)), relating to the co-pay subsidy program described above, and is asserted against defendants BMS and Otsuka on behalf of plaintiffs DC 37, Sergeants, and the class.

147. COUNT THREE is asserted against defendants BMS and Otsuka for the Abilify co-pay subsidy program.

148. This program is referred to as the "co-pay subsidy program." The drug Abilify is referred to as the "subsidized drug."

149. Section 2(c) of the Robinson-Patman Act prohibits the payments by drug manufacturers to, or on behalf of, individual insureds to eliminate or reduce their personal obligations under their prescription drug plans' cost-sharing plans. The relevant part of the statute makes it unlawful for any person engaged in commerce to, in the course of such commerce:

> (1) pay (or receive)-
>
> > (a) anything of value as a commission, brokerage, or other compensation, or

(b) by allowance or discount in lieu of brokerage, *except* for services rendered in connection with a sale or purchase of goods,

(2) when the payment is made to (or by)

(a) the other party to the transaction, or

(b) an agent, representative or other intermediary where the intermediary is

(i) acting for or in behalf of, or

(ii) subject to the direct or indirect control of

(iii) any party to the transaction other than the person by whom the compensation is paid.[30]

150. Generally, these provisions of the Robinson-Patman Act bar commercial bribery, *i.e.*, they prohibit a person from paying off fiduciaries, agents or other intermediaries who control purchasing decisions to be paid for by another. Here, each defendant is a "person" making payment of something of value: defendants pay individual insureds to choose a subsidized drug that is paid for by the individuals' health benefit providers. Paying individuals who receive prescription drug benefits pursuant to plans offered by private health plans qualifies as a violation of Section 2(c) of the Robinson-Patman Act because the subsidies are "anything of value" which are both (i) paid as "compensation" for purchasing the branded drugs, and (ii) as a "discount in lieu of brokerage."

151. Individual insureds who accept rebates under defendants' co-pay subsidy program qualify as "agent[s], representative[s] [and] "other intermediar[ies]" because, pursuant to the terms of their agreements with their health benefit providers, they both (i) act on behalf of their health benefit providers in having substantial control in the choice of which medication will be paid for by the health benefit providers and, (ii) under the terms of the agreements with their

[30] 15 U.S.C. §13(c).

health benefit providers, act subject to their health benefit providers' direct and indirect control in seeking payment for the selected medications through the terms of their plans. But members do not know these co-pay subsidies are bribes.

152. Defendants offer these co-payment subsidies to privately-insured plan members in order to capture the large payments by private health benefit providers that accompany the relatively modest co-payments made by the individual members. By drastically reducing or eliminating the increased cost-sharing obligation, defendants increase sales of subsidized drugs to the detriment of health benefit plans. Health benefit providers (including DC 37 and Sergeants) invest a great deal of actuarial resources to provide incentives for their members to choose less expensive prescription drug therapy that works as well as pricier drugs. Defendants' co-pay subsidy program provides illegal inducements to members to choose more expensive drugs, to the detriment of prescription drug plans provided by DC 37, Sergeants, and members of the class.

153. As a result, defendants' co-pay subsidy program results in injury to DC 37, Sergeants, and the class because the payments result in more purchases of the subsidized drug by plaintiffs and the class than would have been made absent the illegal inducements.

IX. DEMAND FOR JUDGMENT

154. WHEREFORE, plaintiffs DC 37 and Sergeants, on behalf of themselves and the proposed class, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class and declare plaintiffs DC 37 and Sergeants the class representatives;

B. Enter judgment against defendants in favor of DC 37, Sergeants, and the class;

C. Adjudge and decree the acts alleged herein to be unlawful;

D. Award the class damages in an amount to be determined at trial;

E. Award the class threefold damages pursuant to 18 U.S.C. § 1964(c) and 15 U.S.C. § 15(a);

F. Award plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law;

G. Enjoin defendants from offering these or similar co-pay subsidy programs; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by defendants' unlawful conduct as the Court deems just.

X. JURY DEMAND

155. Pursuant to Fed. Civ. P. 38, plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

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Respectfully submitted,

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